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Risk Group's Guidance To Address Uncertainty Issues In TCE Exposures

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A private sector risk assessment group reviewing EPA's cleanup policy related to trichloroethylene (TCE) is drafting guidance to help regulators and consultants assess the risks of short-term exposures to the chemical, including addressing the uncertainty involved in comparing sampling results to the agency's risk levels and determining critical exposure time frames that can lead to negative health effects.

The Alliance for Risk Assessment (ARA), a group of toxicologists and risk assessors from industry, consulting firms and nonprofits, began reviewing EPA's TCE policies in the fall after EPA Region IX proposed a strict new Removal Action Level (RAL) to protect against fetal cardiac defects at the Middlefield-Ellis-Whisman Superfund site in Mountain View, CA. And ARA members met with EPA in November to urge the agency to drop regulation of short-term exposure to TCE, arguing that EPA's intent to protect against cardiac birth defects is based on flawed science (*Risk Policy Report*, Nov. 27).

During a Jan. 8 conference call ARA panelists confirmed they intend to create guidance to help assess short-term exposures and that the document will address the uncertainty involved in comparing sampling results to EPA's Integrated Risk Information System (IRIS) data, as well as uncertainty in reference concentrations (RfCs) -- or the amount of a substance EPA anticipates can be inhaled daily over a lifetime without causing adverse health effects -- and in sampling results themselves.

The group also intends to consider exposure durations for developmental risks -- how long it takes for a health effect from a certain chemical to appear -- and specifically for TCE, whether it is appropriate to use cardiac birth defects as the risk that drives regulation.

Exposure durations are an area that have not been well studied and need further research, ARA members said on the Jan. 8 call. And the group's preliminary work suggests the risk of toxic nephropathy, which can damage kidney function, should form the basis of TCE regulation instead of the risk of fetal cardiac malformation, panelists said.

EPA's RfC for TCE includes the risk for cardiac birth defects, based on a peer-reviewed 2003 study by Paula D. Johnson, though industry continues to argue the science is too uncertain to be used for regulatory purposes.

One source familiar with the issue has said industry's concern may be driven by fears that the proposed RAL may open the door to strict new cleanup requirements and bolster future personal injury and worker protection claims that might be brought against private and federal responsible parties at the hundreds of sites nationwide where TCE is present.

Questions also remain over whether a single spike in TCE levels can prompt cardiac problems, a lack of clarity that is illustrated by the different approaches EPA regions have taken on the issue in the absence of guidance from EPA headquarters.

Region IX's proposed RAL of 15 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) assumes a single exposure for pregnant women above this level could result in fetal cardiac defects, an assumption one toxicologist who has consulted for industry and others say is not supported by the data. "I don't see any real evidence that for cardiac birth defects there is a one-day exact time issue," the source says. "That's just sort of inventing a principal and over-applying it without any evidence."

The lack of clarity of exposure windows prompted Region X in December to recommend a limit of $8.4 \mu\text{g}/\text{m}^3$ in indoor air at commercial and industrial sites to be averaged over any 21-day period. "The available scientific information does not allow for a determination of whether transient spikes in TCE exposures during a 21-day window of early gestation vulnerability may result in

fetal heart malformations, when average media exposure concentrations during that window are not exceeded," Region X said (*Risk Policy Report*, Jan. 8).

While Region X's approach is more consistent with traditional ways of looking at short-term exposures, the toxicologist says, the time frame is still not based on exact science.

ARA members say their guidance will outline principals that can be used to assess risk from TCE and other chemicals with risks from short-term exposures. The document will address uncertainty that arises in three different aspects of risk assessment: uncertainty inherent in estimating an RfC; uncertainties in determining environmental exposures; and uncertainty in comparing measured exposure levels to either an RfC or another limit derived from an RfC. The guidance will also consider whether short-term exposure limits should be derived from chronic numbers, and also the accuracy of these estimates.

The ARA guidance will offer advice for addressing different types of variability in indoor air -- spatial variability, or different levels within one building, and temporal variability over longer periods, sometimes resulting from environmental factors such as changing seasons, according to the call. To address those challenges, ARA will offer guidance on taking multiple samples to address variation and also on assessing data to determine representative concentrations.

In its effort to address uncertainty, the ARA is developing risk ranges around the RfC using methods adapted from case studies, which use different approaches to estimating risk.

The group also plans to consider the issue of exposure durations, or how long it takes for a certain chemical to cause a health effect. The question is especially relevant for chemicals such as TCE where the health effect that drives regulation is derived from animal studies because the exposure duration that may cause a health effect in animals may be different from the time it takes for the same effect to appear in humans, panelists said.

Some studies have suggested it may be possible to extrapolate "exposure windows" for certain chemicals based on the half-life of the compound, one panelist said.

The toxicologist source says toxicology traditionally holds that the likelihood a health effect will occur increases the longer someone is exposed because the chemical builds up in the body, and that toxicologists should account for this when regulating short-term exposures. Even when a short window of exposure causes a health effect, the problem is still the result of a cumulative effect, the source says.

But determining the appropriate exposure windows to accurately regulate different chemicals would be a lengthy process, the source says.

The source adds that in cases where short-term regulation may be appropriate, it is unclear what the exposure window should be for specific chemicals, adding "this has not been well worked through in toxicology."

Regarding TCE, the source says, "there might not be a developmental effect [for TCE] in the first place," but even if there is, one has to study how long the concentration has to be maintained in the body to cause a cardiac birth defect.

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